OCT - 4 2001

K012949

510(k) Summary
For the Sofradim Production
URETEX SUP® Pubourethral Sling and Instruments

1. SPONSOR

Sofradim Production
116 avenue du Formans
01600 Trevoux
France

Contact: Patrice Becker
Telephone: 33 (0)4 74 08 90 00
Facsimile: 33 (0)4 74 08 90 02

2. DEVICE NAME

Proprietary Name:	URETEX SUP® Device
Common/Usual Name:	Surgical Mesh
Classification Name:	Surgical Mesh

3. PREDICATE DEVICES

Ethicon TVT	K974098
Sofradim Parietene® Meshes	K991400
Mentor Sling	K980483

4. DEVICE DESCRIPTION

The URETEX® SUP Pubourethral Sling is used in gynecological procedures for the treatment of stress incontinence. The URETEX® SUP device is made from polypropylene sealed monofilament stitches (tape). It is composed of an insertion instrument, connector, sheath, and the pubourethral implant. The insertion instrument consists of a stainless steel needle with PVC tubing.

5. INTENDED USE

The URETEX® SUP device is indicated for the treatment of stress urinary incontinence in women.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The URETEX® SUP Polypropylene Mesh is substantially equivalent to the T.V.T. Ethicon Prolene Pubourethral Tape, the Sofradim Parietene® Mesh, and the Mentor Sling Device.

The URETEX® SUP Polypropylene Mesh and the TVT device have the same intended use in that they are all used for treatment of stress urinary incontinence.

The URETEX SUP, the TVT Ethicon (Prolene® mesh), the Mentor Sling and the Parietene® Polypropylene Mesh are all made from polypropylene sealed monofilament stitches. All of the devices are single-use only.

7. PERFORMANCE TESTING

Testing was performed in accordance with ISO standards. The density, thickness, elongation, breaking strength, tear resistance, burst resistance, and tensile strength were evaluated to determine the performance characteristics of the Pubourethral Sling. All of the testing was performed using the URETEX® SUP Sling, the Ethicon Prolene®, and the Sofradim Parietene® predicate devices for comparative purposes. The test results showed that the Sofradim and predicate devices were similar in performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 4 2001

Sofradim Production
c/o Ms. Mary McNamara-Cullinane
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K012949
Trade/Device Name: Sofradim URETEX® SUP Pubourethral Sling and Instruments
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: August 29, 2001
Received: September 4, 2001

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walter, MD

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012949

Device Name: Sofradim URETEX® *SUP* Pubourethral Sling and Instruments

Indications For Use:

The URETEX® SUP device is intended to be used as a pubourethral sling for the treatment of stress urinary incontinence in women resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012949

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)